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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,150	07/17/2003	Robert W. Childers	DI-5828	5656

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EXAMINER

SCHELL, LAURA C

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/624,150

Applicant(s)

CHILDERS ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 13 and 24, and consequently all dependent claims, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear to the examiner how Applicant can claim that the fluid loop consists of "only a single fluid loop" as the elected species, Figs. 5a and 5b, consists of multiple fluid loops such as:

A loop starting in the patient (136) continuing through the second pump (128) through the arrow marked (100ml/min) through (140), through (166) and back out to the patient, which constitutes one loop. A second loop would go through the same elements and follow the same route until right before it goes back out the patient and right before it passes through the pressure and temp sensors (142 and 144), where it can follow a different path up to the first pump, for example, and then follow the path of the arrow out of the first pump, down through (164), through (166) and then right before it hits the temperature and pressure sensors again, it could follow that path to the third pump and be pumped down to the last bag of therapy fluid (152), for example. Or, once it hits the third pump, it follow an entirely different flow path/loop by taking any number of the paths off of each pump. Clearly, this is not just a single fluid loop.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5 and 8-11, 13, 15, 17, 18, 20, 23-28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu et al. (US Patent No. 6,254,567) in view of Brugger et al. (US Patent No. 5,776,091). Treu discloses a system for providing peritoneal dialysis to a patient, the system comprising: a catheter having an inflow lumen and an outflow lumen in communication with the patient's peritoneal cavity (col. 6, line 6); a fluid circuit in fluid communication with the catheter (Fig. 7), the fluid circuit consisting of: a fluid loop configured to circulate a therapy fluid into, through and out of a peritoneal cavity of the patient (Fig. 7); a supply of dialysate coupled to the fluid circuit; a cyclor (14) that pumps the dialysate into the fluid circuit (also see col. 4, lines 17-24) at a feed rate and circulates the dialysate at a circulation rate along the fluid loop to remove a therapeutic effective amount of solutes and excess water from the patient; and a discharge fluid path coupled to the fluid loop through which the therapy fluid is drained from the fluid circuit at a discharge rate (see col. 9, line 52 through col. 10, line 48). Treu, however, does not disclose that the discharge rate is less than the circulation rate, allowing the therapy fluid to be circulated a plurality of times along the fluid loop

prior to discharge. Brugger, however, does disclose using a discharge rate that is less than the circulation rate, and therefore would allow the therapy fluid to be circulated a plurality of time along the fluid loop before discharge. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Treu with the flow rates as taught by Brugger in order to provide a system that is effective in maximizing the amount of solutes and water. Treu also discloses that the dialysate can be heated and mixed (col. 5, line 40). Treu also discloses a cleaning device coupled to the fluid loop via a cleaning fluid path wherein the therapy fluid including the dialysate can be fed into the cleaning fluid path and cleaned at a cleaning rate prior to reintroduction into the fluid loop (col. 3, lines 10-15). Treu also discloses that the cyclor can include a plurality of valves for controlling flow (col. 5, line 39).

In reference to claims 2-5, 12, 16, 19, 21, Treu does not disclose the various rates as claimed. However, it would have been obvious to one of ordinary skill in the art to vary the rates of pumps and vary the opening of the valves to reach the desired effective flow rate (see col. 9, line 52 through col. 10, line 48).

Claims 6, 7, 14, 22 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Treu in view of Brugger and further in view of Ash (US Patent No. 6,409,699). Treu in view of Brugger discloses the device substantially as claimed except for the volume of dialysate and the length of the treatment period. Ash, however, discloses that the supply of dialysate is 20 liters, which falls within the claimed "about 25 liters or less or dialysate" and the treatment period is 8 hours (col. 15, lines 10-11 and line 44). Therefore it would have been obvious to one of ordinary skill in the

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art to have modified Treu in view of Brugger with the volume and time limits as taught by Ash, as these limitations are well known and used within the art of peritoneal dialysis.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 8am-4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

